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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/942,137	08/29/2001	Christopher M. Angelucci	8932-538	6603

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JONES DAY  
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NEW YORK, NY 10017-6702

EXAMINER
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REIMERS, ANNETTE R

ART UNIT	PAPER NUMBER
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3733

DATE MAILED: 05/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

### Period for Reply

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1) ☒ Responsive to communication(s) filed on 04 January 2006.

2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

4) ☒ Claim(s) 1-8, 13-21, 23-25, 27 and 53-74 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) ☒ Claim(s) 23-25, 27, 53-68 and 72-74 is/are allowed.

6) ☒ Claim(s) 1-8, 13, 14, 16-21 and 69-71 is/are rejected.

7) ☒ Claim(s) 15 is/are objected to.

8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

9) ☒ The specification is objected to by the Examiner.

10) ☒ The drawing(s) filed on 21 August 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All    b) ☐ Some \*    c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.

4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.

5) ☐ Notice of Informal Patent Application (PTO-152)

6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Specification***

The disclosure is objected to because of the following informalities: In claim 1, lines 5-6, applicant is requested to further clarify in the specification "the hollow region comprising most of the volume of the body portion." Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-2, 5-6, 16-21 and 69 are rejected under 35 U.S.C. 102(e) as being anticipated by Shapiro et al. (US Patent Number 6,436,139).

Shapiro et al. disclose an implant comprising a body portion 10 having a length, a width and a depth (see figures 2-3). The body is insertable, i.e. capable of being inserted, between first and second cut bone segments. The body portion has an outer surface and an inner surface defining a substantially hollow region, 44, wherein the hollow region comprises most of the volume of the body portion. The body portion further has first and second ends that communicate with the hollow portion (see figures 2-3). The first and second ends comprise bone engaging portions having a single bone

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receiving channel, 38, that has a first depth relative to a first side region of the outer surface and a second depth relative to a second side region of the outer surface, the first and second depths having different measurements, the first and second side regions having substantially the same contour (see figures 2-3). The perimeter of the outer surface of the implant is a geometric circular/tubular shape (see figures 2-3). The channel includes at least two angled faces and they have an arcuate shape (see figures 2-3). The implant further includes at least one hole or opening in communication with the outer surface and the inner surface (see figures 2-3). The implant is fabricate from biocompatible metal or another such material (see column 8, lines 37-40).

With regard to the statement of intended use and other functional statements, they do not impose any structural limitations on the claims distinguishable over Shapiro et al., which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference “teach” what the subject patent teaches, but rather it is only necessary that the claims under attack “read on” something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3-4, 7-8, 13-14 and 70-71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shapiro et al. (US Patent Number 6,436,139).

Shapiro et al. disclose the claimed invention except for the geometric shape being an ellipse. It would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct the implant of Shapiro et al. having a geometric shape like an ellipse, since applicant has not disclosed that such solve any stated problem or is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of adapting the implant to the implant site. In re Dailey and Eilers, 149 USPQ 47 (1966).

With regard to claims 4 and 70, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the implant of Shapiro et al. having a length ranging from about 11.5 to about 15.5 mm, a width ranging from about 8.0 to about 9.0 mm, and a depth ranging from about 5.5 to about 6.5 mm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

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With regard to claim 71, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the implant of Shapiro et al. having a tubular wall thickness of about 1.0mm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

With regard to claims 7-8 and 13-14, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the implant of Shapiro et al. from bone allograft material, or demineralized cortical bone, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1-8 and 13-21 have been considered but are moot in view of the new ground(s) of rejection.

### ***Allowable Subject Matter***

Claim 15 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 23-25, 27, 53-68 and 72-74 are allowed.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Annette R. Reimers whose telephone number is (571) 272-7135. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AR

AK

A handwritten signature in black ink, appearing to read 'ER', is positioned above the printed name of the examiner.

EDUARDO C. ROBERT  
SUPERVISORY PATENT EXAMINER